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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,751	02/09/2004	Jerry R. Grychowski	6298-449	6148
757	7590	02/08/2006	EXAMINER	
BRINKS HOFFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			PATEL, NIHIL B	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 02/08/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/774,751	Applicant(s) GRYCHOWSKI ET AL.	
	Examiner Nihir Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11.29.2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
 4a) Of the above claim(s) 2 and 15-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-14 is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 24-31 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to **claims 1, 3-14 and 24-31** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1, 3, 4, 9, 24-27, 29 and 30** are rejected under 35 U.S.C. 102(b) as being anticipated by Farmer (US 2002/0069870). **Referring to claim 1**, Farmer discloses an apparatus that comprises a chamber housing **14** (see **figure 1**) defining an interior space and comprising an input end and an output end (see **figure 1**); a one way valve **16** positioned upstream of the interior space, the one way inhalation valve operative to permit a flow of gas into the interior space of the chamber housing (see **figure 1 and page 2 paragraph [0022]**); a first inhalation conduit **17** communicating with the output end of the chamber, the inhalation conduit adapted to transmit medication to the patient (see **figure 1 and page 2 paragraph [0022]**); a second inhalation conduit (see **figure 1; the portion located next the one way valve 16**) communicating with the input end of the chamber housing wherein the one-way inhalation valve is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve; an exhaust conduit (see **figure 1; the portion located just before the exhaust valve 21**) communicating with the first inhalation

conduit 17; and a one way exhaust valve 21 located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the first inhalation conduit.

Referring to claim 3, Farmer discloses an apparatus that further comprises pressurized metered dose inhaler 11 in flow communication with the chamber housing downstream of the one way inhalation valve (see figure 1).

Referring to claim 4, Farmer discloses an apparatus wherein the second inhalation conduit comprises an adaptor having an output end connected to the input end of the chamber housing an input end connected to the oxygen intake line, the adapter having the one-way inhalation valve disposed therein (see figure 1).

Referring to claim 9, Farmer discloses an apparatus wherein the first inhalation conduit comprises a mask 18 (see figure 1).

Referring to claim 24, Farmer discloses a method step that comprises transmitting oxygen from a gas source through a holding chamber and inhalation conduit to the patient during an inhalation sequence of a breathing cycle; introducing the medication into the holding chamber 14; preventing a substantial transmission of an exhaust gas into the holding chamber during an exhalation sequence of the breathing cycle; transmitting a substantially portion of the exhaust gas into an exhaust conduit during the exhalation sequence; and preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences of subsequent breathing cycles.

Referring to claim 25, Farmer discloses a method step of preventing the substantial transmission of the exhaust gas into the holding chamber during the exhalation sequence comprising creating a back pressure in the holding chamber.

Referring to claim 26, Farmer discloses a method step of creating the back pressure in the holding chamber comprises providing a one-way valve between the gas source and the holding chamber, and preventing the flow of the exhaust gas from the holding chamber toward the gas source with the one way valve.

Referring to claim 27, Farmer discloses a method step of preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences comprises providing a one way valve in the exhaust conduit, and preventing the flow of the exhaust gas from the exhaust conduit to the inhalation conduit with the one-way valve.

Referring to claim 29, Farmer discloses an apparatus wherein the second inhalation conduit is isolated from and does not communicate with ambient air.

Referring to claim 30, Farmer discloses an apparatus wherein the oxygen intake line and the exhalation conduit are connected to a ventilator (**see paragraph [0004]**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **6 and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 2002/0069870) in view of Bayron et al. (US 6,886,561). **Referring to claim 6**, Farmer discloses the applicant's invention as claimed with the exception of providing a valve member that is a center post valve member connected to the valve seat. Bayron discloses an apparatus that does provide a valve member that is a center post valve member connected to the valve seat (see **column 5 lines 54-60**). Therefore it would have been obvious to modify Farmer's invention by providing a valve member that is a center post valve member connected to the valve seat as taught by Bayron in order to have better control of gas delivery.

Referring to claim 7, Farmer discloses the applicant's invention as claimed with the exception of providing a blocking member that has at least one opening formed therein to permit flow of gases therethrough. Bayron discloses an apparatus that does provide a blocking member

that has at least one opening formed therein to permit flow of gases therethrough (see **column 5 lines 24-30**). Therefore it would have been obvious to modify Farmer's invention by providing a blocking member that has at least one opening formed therein to permit flow of gases therethrough as taught by Bayron in order to have better control of delivery.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,269,810) in view of Bird (US 6,581,600). **Referring to claim 8**, Brooker discloses the applicant's invention as claimed with the exception of providing an inhalation conduit that comprises an endotracheal tube. Bird discloses an interface apparatus and combination and method that does provide an inhalation conduit that comprises an endotracheal tube. Therefore it would have been obvious to modify Brooker's invention by providing an inhalation conduit that comprises an endotracheal tube as taught by Bird in order to provide better way of delivering the medication.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 2002/0069870) in view of Richardson et al. (US 6,279,574). **Referring to claim 28**, Farmer discloses the applicant's invention as claimed with the exception of providing WYE connector connecting the second inhalation conduit and the exhaust conduit. Richardson discloses an apparatus that does provide WYE connector connecting the second inhalation conduit and the exhaust conduit. Therefore it would have been obvious to modify Farmer's invention by providing WYE connector connecting the second inhalation conduit and the exhaust conduit as taught by Richardson in order to provide better way of delivering the medication.

Allowable Subject Matter

Claims **11 through 14** are allowed.

Claim **10** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel
January 24th, 2006



Henry Bennett
Supervisor, Patent Examiner
Group 3700